AMENDED CLAIMS
received by the International Bureau on 30 January 2006 (30.01.2006)
871 original claims 1-22, replaced by amended claims 1-22.

What we claim is:

1. A process for the preparation of the α-crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl)pyrimidin-2-ylamino]phenyl]benzamide comprising:

a) carrying out the addition reaction using not more than 0.99 equivalents of methanesulfonic acid per 1 equivalent of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide, in a solvent selected from the group consisting of C_2-C_6 aliphatic alcohols or the mixtures thereof, optionally with the addition of the other C_1-C_4 aliphatic alcohol;

b) adding, if necessary, a solvent selected from the group consisting of the esters of lower carboxylic acids and C_1-C_4 aliphatic alcohols;

c) optionally inoculating the reaction mixture with the α-crystal form;

d) stirring the reaction mixture for the time necessary for crystallization of the α-crystal form;

e) isolating the α-crystal form from the reaction mixture.

2. The process according to claim 1 in which the addition reaction is carried out using from 0.95 to 0.99

4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl] benzamide.

3. The process according to Claims 1-2, in which the addition reaction is carried out in an alcohol selected from the group comprising *n*-propyl alcohol, isopropyl alcohol, *n*-butyl alcohol, *tert*-butyl alcohol and the mixtures thereof with ethyl alcohol.

4. The process according to Claims 1-3 in which the addition reaction is carried out in the mixture containing from 0 to 50% of ethyl alcohol and from 50 to 100% of n-propyl alcohol (v/v).

5. The process according to Claims 1-3 in which the addition reaction is carried out in the mixture containing from 0 to 50% of ethyl alcohol and from 50 to 100% of isopropyl alcohol (v/v).

6. The process according to Claims 1-3 in which the addition reaction is carried out in the mixture containing from 0 to 50% of ethyl alcohol and from 50 to 100% of n-butyl alcohol.

7. The process according to Claims 1-3 in which the addition reaction is carried out in the mixture containing from 0 to 50% of ethyl alcohol and from 50 to 100% of *tert*-butyl alcohol.

8. A process for the preparation of the α-crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl)pyrimidin-2-ylamino]phenyl]benzamide comprising:

a) carrying out the addition reaction using 1 equivalent of methanesulfonic acid per 1 equivalent of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in the ethyl alcohol, optionally with the addition of the other C_1-C_4 aliphatic alcohol;

b) adding a solvent selected from the group consisting of the esters of lower carboxylic acids and C_1-C_4 aliphatic alcohols;

c) inoculating the reaction mixture with the α-crystal form;

d) stirring the reaction mixture for the time necessary for crystallization of the α-crystal form;

e) isolating the α-crystal form from the reaction mixture.

8a. The process according to claim 8 in which the additional C_1-C_4 aliphatic alcohol is methyl alcohol or isopropyl alcohol and wherein the proportion of C_1-C_4 aliphatic alcohol in a solvents mixture do not exceed 55% (v/v).

10. The process according to Claims 1-8a in which the addition reaction is carried out with stirring while maintaining internal temperature of the mixture within the range from room temperature to boiling temperature of the reaction mixture.

11. The process according to Claims 1-8a in which the α-crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide thus obtained is essentially free of the β-crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide or any other crystalline solids.

12. The process according to Claims 1-11 in which the α-crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide thus obtained shows on X-ray powder diffraction diagram peaks at 2θ angles of approximately: 4.9; 18.6; 19.1; 23.2 and 28.6°, obtained for radiation of CuKα and the wavelength λ=1,54056 Å.

13. The process according to Claims 1-12 in which the α-crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide thus obtained shows on X-ray powder diffraction diagram the peaks of relative intensity over 20% at 2θ angles of approx.: 10.5; 14.9; 16.5; 17.7; 18.1; 18.6; 19.1; 21.3; 21.6; 22.7; 23.2; 23.8; 24.9; 27.4; 28.0 and 28.6°.

14. Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide.

15. Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in a crystalline form.

16. Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in a crystalline Form I which shows on X-ray powder diffraction diagram obtained for radiation of CuKα at the wavelength λ=1.54056 Å peaks of relative intensity over 20% at 2θ angles about: 16.94, 19.80, 20.08, 20.51, 21.28, 21.65, 21.98, 22.70 and 23.07°.

16. Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in a crystalline Form I according to Claim 15, characteristic in that its X-ray powder diffraction diagram obtained for radiation of CuKα at the wavelength λ=1.54056 Å is essentially identical with that presented on Fig. 8.

17. Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in a crystalline Form II which shows on X-ray powder diffraction diagram obtained for radiation of CuKα at the wavelength

λ=1.54056 Å peaks of relative intensity over 20% at 2θ angles about: 17.23, 17.62, 18.72, 19.90, 20.23, 21.25, 21.59, 22.05, 22.44, 23.38, 23.68, 24.48, 25.41, 26.10 and 28.39°.

18. Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in a crystalline Form II according to Claim 17, characteristic in that its X-ray powder diffraction diagram obtained for radiation of CuKα at the wavelength λ=1.54056 Å is essentially identical with that presented on Fig. 9.

19. A mixture of the crystalline Forms I and II of dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide which shows on X-ray powder diffraction diagram obtained for radiation of CuKα at the wavelength λ=1.54056 Å peaks of relative intensity over 20% at 2θ angles about: 16.91, 17.60, 18.69, 19.78, 20.50, 21.60, 22.00, 22.70, 23.07, 24.49, 26.13 and 27.25°.

20. The mixture of the crystal Forms I and II of Dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide according to Claim 19, characteristic in that its X-ray powder diffraction diagram obtained for radiation of CuKα at

the wavelength λ=1.54056 Å is essentially identical with that presented on Fig. 10.

21. The use of any of the crystalline form of dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide selected from the group comprising the Forms I and II and the mixtures thereof, for the preparation of a pharmaceutical composition having anti-neoplastic activity.

22. The pharmaceutical composition of dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide selected from the group comprising the crystalline forms I and II and the mixtures thereof, together with the pharmaceutically acceptable carriers and/or excipients.